

REMARKS

Claims 8-14 are currently pending in this application. Reconsideration is respectfully requested in light of the above claim amendments and the following remarks.

The Examiner rejected claims 8 and 14 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,697,965 to Griffin in view of U.S. Patent 5,571,161 to Starksen. Applicants respectfully traverse these rejections.

Independent claim 8 recites a lead implant system comprised in part by a guide wire that is slidably receivable through a longitudinally extending passage of a stylet, the combined stylet and guide wire being configured for slidable introduction into an elongated tubular lead body for cooperatively implanting a distal end of the lead at a desired location, and wherein the guide wire is configured for extension beyond a distal end of the stylet. (Underlining added for emphasis only). Applicants respectfully submit that cited references do not disclose or suggest the recited claim elements.

The Examiner admits that Griffin does not disclose a combined stylet and guide wire. The Examiner alleges however that Starksen discloses an elongated stylet having an internal passage extending longitudinally through the stylet and a guide wire that is slidably receivable in the internal passage of the stylet. The Examiner further alleges that it would have been obvious to one of ordinary skill in the art to combine Griffin and Starksen because the combination would provide easy maneuvering of a lead to the desired location. Applicants respectfully disagree.

It is well understood that there must be some suggestion in the references that they be combined to support an obviousness rejection. Merely picking and choosing among various references is not permitted, and doing so amounts to no more than mere hindsight reconstruction. One of ordinary skill in the art must be motivated by the teachings to combine the references, without using applicants' claimed invention as a guide. Further, the strongest rationale for combining references is a recognition, either expressly or impliedly, in the prior art, that some advantage or expected beneficial result would be produced by the proposed combination of references. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). In addition, it is improper to

combine references where the references teach away from the combination. In re Grasselli, 713 F.2d 731, 743; 218 USPQ 769, 779 (Fed. Cir. 1983), see MPEP section 2145(X)(D)2).

The Examiner suggests that the motivation to combine Griffin and Starksen is to provide a system and method which provides for easy maneuvering of a lead or catheter to a desired location. However, there is no teaching, impliedly or expressly in Griffin or Starksen that a combination stylet/guidewire would provide easy maneuvering of a lead. Rather, Griffin discloses a catheter, adapted for temporary placement in a patient for performing atrial defibrillation. Further, as the Examiner, notes the catheter of Griffin is adapted to accept either a stylet or guidewire for placement but does not in anyway disclose or suggest a combined stylet and guidewire, nor is there any indication that such a combination would be helpful in placing the catheter of Griffin.

In addition, Griffin does not teach or suggest that a technique that may be effective in placing the steerable catheter taught by Starksen would be equally effective in placing an electrical lead. Thus, Griffin does not provide a motivation to combine.

Similarly, Applicants submit that Starksen does not provide a motivation to combine. Rather, Starksen teaches away from the proposed combination. For example, Starksen teaches that transvenous placement of the electrical leads for an implantable pacemaker can be problematic. Starksen further states that at present, the leads are usually positioned using an internal stiffening stylet which is used to guide the distal end of the lead under fluoroscopic imaging. Since the leads lack column strength and there is substantial blood flow through the heart chambers, manipulating a lead is difficult and positioning of the lead is not always accurate. (Starksen, col. 1, lines 32-39).

Starksen therefore discloses the use of a steerable guide catheter for placement of electrical leads for cardiac pacemakers and the like (See Abstract). Thus, Starksen clearly teaches away from direct placement of electrical leads using a stylet and or guide wire due to perceived difficulties in accurately positioning the lead at a desired location using these devices and instead utilizes a steerable guide catheter to place a lead.

Accordingly Applicants respectfully submit that claim 8 is novel and non-obvious over Griffin and Starksen and is therefore allowable. Applicants further submit that claim 14 that depends from claim 8, is allowable as is claim 8 and for additional limitations recited therein.

The Examiner rejected claims 9, 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Griffin, in view of Starksen as applied to claim 8 and further in view of U.S. Patent 5,129,404 to Spehr et al. , U.S. Patent Publication 2003/0191515 to Hadelman et al. or U.S. Patent 6,944,506 to Morgan et al. In view of the foregoing analysis of independent claim 8 in view of Griffin and Starksen, Applicants believe that the rejection of dependent claims 9, 12 and 13 under §103 is rendered moot as claim 9, 12 and 13 depend from allowable independent claim 8.

The Examiner rejected claims 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Griffin, in view of Starksen as applied to claim 8 and further in view of Re. 33,911 to Samson et al. In view of the foregoing analysis of independent claim 8 in view of Griffin and Starksen, Applicants believe that the rejection of dependent claims 10-11 under §103 is rendered moot as claim 10-11 depend from allowable independent claim 8.

The Examiner rejected claim 8 under 35 U.S.C. § 103(a) as being obvious over Haldeman et al. or Morgan et al. in view of Starksen. Applicants respectfully traverse these rejections.

Applicant respectfully submits that, Morgan et al. only qualifies as prior art to the subject matter claimed in the present application, if at all, under 35 U.S.C. § 102(e). Applicants further submit that Morgan et al. was filed after November 29, 1999 and is assigned to a common assignee as the present application. Therefore, under 35 U.S.C §103(c), Morgan et al. can not be used as a prior art reference to support a rejection of the pending claims under 35 U.S.C §103(a). Applicants therefore respectfully request that this rejection be withdrawn.

Further, the Examiner again admits that Haldeman et al. do not disclose a combined stylet and guide wire. The Examiner alleges however that Starksen discloses an elongated stylet having an internal passage extending longitudinally through the stylet and a guide wire that is slidably receivable in the internal passage of the stylet.

The Examiner further alleges that it would have been obvious to one of ordinary skill in the art to combine Haldeman et al. and Starksen because the combination would provide easy maneuvering of a lead or catheter to a desired location. Applicants respectfully disagree.

As argued above, there must be some suggestion in the references that they be combined to support an obviousness rejection. The Examiner again suggests that the motivation to combine Haldeman et al. with Starksen is to provide easy maneuvering of a lead or catheter to the desired location. However, there is no teaching, impliedly or expressly in Haldeman et al. or Starksen that a combination stylet/guide wire would provide easy maneuvering of a lead. Rather, the lead of Haldeman et al. is adapted to accept either a stylet or guidewire for placement but does not in anyway disclose or suggest a combined stylet and guidewire, nor is there any indication that such a combination would be helpful in placing the lead of Haldeman et al.

In addition, Haldeman et al. does not teach or suggest that a technique that may be effective in placing a steerable catheter as taught by Starksen would be equally effective in placing an electrical lead. Thus, Haldeman et al. does not provide a motivation to combine.

Similarly, Applicants submit that Starksen do not provide a motivation to combine. Rather, Starksen teaches away from the proposed combination. For example, Starksen teaches that transvenous placement of the electrical leads for an implantable pacemaker can be problematic. Starksen further teaches that at present, the leads are usually positioned using an internal stiffening stylet which is used to guide the distal end of the lead under fluoroscopic imaging. Starksen also suggests that since the leads lack column strength and there is substantial blood flow through the heart chambers, manipulating a lead is difficult and positioning of the lead is not always accurate. (Starksen, col. 1, lines 32-39). Starksen therefore discloses the use of a steerable guide catheter for placement of electrical leads for cardiac pacemakers and the like (See Abstract). Thus, Starksen clearly teach away from direct placement of electrical placement of electrical leads due to perceived difficulties in accurately positioning the lead at a desired location and instead utilizes a steerable guide catheter.

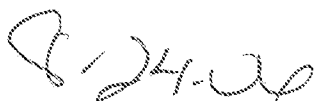
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Applicants therefore respectfully submit that neither Haldeman et al. or Starksen provide a motivation to combine.

Accordingly applicants respectfully submit that claim 8 is novel and non-obvious over Haldeman et al. and Starksen and is therefore allowable.

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,



Date



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